

**Appln No. 10/562,368**  
**Amdt date July 14, 2008**  
**Reply to Office action of February 25, 2008**

**REMARKS/ARGUMENTS**

Claims 1-24 are pending in the above-referenced application.

Claims 5-16 have been amended to more correctly depend from other claims. Claims 17 to 24 have been added to further define the Applicant's invention. No new matter has been added.

This is a response to the non-final Office Action dated February 25, 2008 wherein the Examiner rejected: (1) claims 1-4 under 35 U.S.C. 102(b) as being anticipated by Loretto (EP 0965443 A1); and (2) objected to claims 5-16 under 37 CFR 1.75(c) for improperly dependent on another multiple dependent claim, and consequently did not consider them until they are corrected.

As indicated above, the claims have been amended to address the objection for improper dependency to another multiple dependent claim and to further define Applicant's invention. Applicant submits that the amended claims, as well as the newly added claim, clearly distinguish over the art of record and therefore obviate the rejection.

In view of the amended claims and the remarks that follow, reconsideration and a notice of allowance are respectfully requested.

**§102 (b) Rejection of Claims 1-4 over Loretto (EP 0965443 A1)**

Claims 1-4 are rejected under 35 U.S.C § 102(b) as being anticipated by Loretto.

In rejecting the foregoing claims, the Examiner takes the position that the cited reference teaches all the elements and limitation of the pending claims either explicitly or inherently.

Preliminarily, for a reference to anticipate a claimed invention under §102(b), it must adequately meet the terms of the claimed invention interpreted in light of the specification of the application. As set forth in the statute, the single prior art reference must disclose each and every element of the claim under consideration. Moreover, it

cannot be rebuilt or reoriented by the utilization of Applicant's teachings in an attempt to create an anticipatory structure.

Claim 1 recites:

Sterilizable multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, optionally in a spatially separated arrangement of the contents, having a three-layered structure with an inner layer being in contact with the content of the container, an intermediate layer and an outer layer facing the environment, said layers optionally connected by tie and/or adhesive layers, wherein:

the oxygen transmission rate at 23°C through the multilayer film determined by the oxygen transmission of the intermediate layer is less than 0.7ml/m<sup>2</sup>d;

said inner layer having a thickness of from 30 to 120 µm;

said intermediate layer having a thickness of from 5 to 35 µm and said outer layer having a thickness of from 20 to 40 µm; and

allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C.

Thus, claim 1 makes clear that the oxygen transmission rate at 23°C through the claimed multilayer film determined by the oxygen transmission of the intermediate layer is less than 0.7ml/m<sup>2</sup>d, the outer layer of the claimed multilayer film has a thickness of from 20 to 40 µm, and allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C.

In contrast, the cited reference EP 0 965 443A1 discloses a sterilizable polymer composite tubular film having a three-layer structure: a homophase polypropylene inner layer "c)" of thickness from 60 to 100 µm, especially from 65 to 85 µm (col. 3, lines 29-33); an ethylene/vinyl alcohol core layer "b)" of thickness from 5 to 35 µm, especially

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from 10 to 30  $\mu\text{m}$  (col. 3, lines 9-11); and an outer layer “a)” of thickness of 40 to 100  $\mu\text{m}$ , especially from 45 to 75  $\mu\text{m}$  (col. 3, line 21-23), made of polyamide 11, commercially available under the tradename of Rilsan (col. 2, lines 53-54) and/or polyetherblock amide, commercially available under the trademark of Pebax<sup>®</sup> (col. 2, lines 55-56).

Applicant would like to point out that even though the lower limit of the outer layer “a)” overlaps with the upper limit of the claimed outer layer, this overlap does not constitute anticipation. Indeed, the cited reference discloses a thickness range of 40 to 100  $\mu\text{m}$  for the outer layer “a)”, but teaches “especially from 45 to 75  $\mu\text{m}$ ” (col. 3, line 21-23) and in the example given teaches an outer layer “a)” of 50 $\mu\text{m}$  thickness, made of polyamide 11 [paragraph 0027]. Furthermore, nowhere in the cited reference is disclosed or suggested the characteristics of an outer layer “allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C”, as recited in part by claim 1.

Applicant respectfully submits that the cited reference fails to anticipate the claimed multilayer film under §102, since it fails to disclose each and every element under consideration; as nowhere in the cited reference is disclosed a sterilizable multilayer film for containers, wherein the oxygen transmission rate at 23°C through the multilayer film determined by the oxygen transmission of the intermediate layer is less than 0.7ml/m<sup>2</sup>d, and an outer layer having a thickness of from 20 to 40  $\mu\text{m}$ , and allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C, as recited in part by claim 1. Since claims 2-16 depend from claim 1, they too are allowable for at least the same reasons and allowance is respectfully solicited.

With regard to the properties of the claimed multilayer film, wherein the oxygen transmission rate at 23°C through the multilayer film determined by the oxygen transmission of the intermediate layer is less than 0.7ml/m<sup>2</sup>d, and an outer layer having a

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thickness of from 20 to 40  $\mu\text{m}$ , and allowing desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121°C; properties that are NOT disclosed or suggested in the cited reference, the Examiner takes the position that:

...such properties limitations are inherent in the multilayer structure taught by Lorette given that the structure of the multilayer film (i.e., the number of layers, etc.) and the chemical composition of each layer within the multilayer film [are] identical to that of the claimed multilayer film. (page 3, instant Office Action, emphasis added).

Applicant respectfully disagrees with the Examiner's position.

With respect to inherent properties, MPEP 2112 states:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). **"To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'**(Emphasis added).

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)

In other words, to state that the claimed properties are inherent to the referenced multilayer film, the claimed properties should be consistently present for the entire

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disclosed thickness range, as inherency may not be established by probabilities or possibilities. Moreover, the prior art must disclose materials that necessarily and predictably give rise to the same claimed properties at all times, not by chance or probabilities. The burden is on the Examiner to provide support why the claimed properties are inherent to the reference multilayer film, as the outer layer of the claimed multilayer film is of thickness 20 to 40  $\mu\text{m}$ , whereas the outer layer "a" of the referenced film is 40 to 100  $\mu\text{m}$ , especially from 45 to 75  $\mu\text{m}$  (col. 3, line 21-23). The burden is on the Examiner to show why and how a 100  $\mu\text{m}$  thick referenced outer layer "a" should "allow desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121° C" resulting in "the oxygen transmission rate at 23° C through the multilayer film determined by the oxygen transmission of the intermediate layer is less than 0.7ml/  $\text{m}^2\text{d}$ " in the exact same way as the claimed outer layer which has a thickness of 20 to 40  $\mu\text{m}$ .

Furthermore, the claimed outer layer is also distinct from the referenced outer layer "a" in that the claimed outer layer "allow[s] desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121° C". The cited prior art discloses an outer layer made from Polyamide 11 and/or polyetherblock amide. No disclosure was made in the specification or in the Office Action regarding whether polyamide 11 and/or polyetherblock amide have such properties. Nor can it be assumed as Applicant is not aware of such characteristics for polyamide 11 and/or polyetherblock amide. In the specification of the instant application, the outer layer is described as comprising or substantially consisting of polyethylene terephthalate homopolymer and/or polyethylene terephthalate copolymer (claim 6) which enables the claimed characteristics in claim 1. Again, in contrast, the referenced outer layer is made of polyamide 11 (col. 2, lines 53-54) and/or polyetherblock amide (col. 2, lines 55-56).

In view of the foregoing remarks, Applicant respectfully submits that the cited reference fails to anticipate the claimed multilayer film, since it fails to disclose, either explicitly or inherently, each and every element of the claim under consideration as

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required by §102(b). Since claims 2-17 directly or indirectly depend from claim 1, they too are allowable over the Loretto reference and allowance is respectfully solicited.

New claim 18 recites: A multilayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, comprising: an inner layer consisting essentially of non-polar polymeric material, an outer layer facing the environment, said outer layer comprising or substantially consisting at least one of polyethylene terephthalate homopolymer and polyethylene terephthalate copolymer; and an intermediate layer, interposed between the inner layer and the outer layer, said intermediate layer comprising or substantially consisting of ethylene/vinyl alcohol copolymer, having a defined ethylene content of 27 to 38, in particular 29 to 32 mol%. As nowhere in the cited reference is disclosed "an outer layer facing the environment, said outer layer comprising or substantially consisting at least one of polyethylene terephthalate homopolymer and polyethylene terephthalate copolymer", as recited in part by claim 18, Applicant submits that claim 18 is patentable over Loretto. Claim 19 depends from claim 18 and thus is also allowable over the cited prior art.

New claim 20 recites a method for forming a multiplayer film for containers containing solutions, suspensions, solids or mixtures for parenteral or enteral nutrition or tube feeding, having an oxygen transmission rate at 23°C through the multilayer film of less than 0.7 ml/m<sup>2</sup>d, the method comprising: providing an inner layer, being in contact with the content of the container, having a thickness of from 30 to 120 µm, providing an outer layer, facing the environment, having a thickness of from 20 to 40 µm, providing an intermediate layer, interposed between the inner layer and the outer layer, having a thickness of from 5 to 35 µm, and wherein the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C. As nowhere in the cited reference is disclosed a method for forming a multiplayer film for containers providing

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an outer layer, facing the environment, having a thickness of from 20 to 40  $\mu\text{m}$ , and wherein the outer layer allows desorption of water absorbed in the intermediate layer during sterilization after said sterilization at 121 °C, as recited in part by claim 20, Applicant submits that claim 20 is patentable over Lorette. Claims 21 to 24 depend from claim 20 and therefore are also patentable over the cited prior art for at least the same reasons and allowance is respectfully solicited.

In view of the amendments and the remarks set forth above, the application is thought to be in condition for allowance.

Should the Examiner find it necessary to speak with Applicant's agent, she is invited to contact the undersigned at the telephone number indicated below.

Respectfully submitted,  
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